



Complete Summary

GUIDELINE TITLE

ACR Appropriateness Criteria® endometrial cancer of the uterus.

BIBLIOGRAPHIC SOURCE(S)

Lee SI, Andreotti RF, Angtuaco TL, Fleischer AC, Horrow MM, Javitt MC, Lev-Toaff AS, Scoutt LM, Zelop C, Expert Panel on Women's Imaging. ACR Appropriateness Criteria® endometrial cancer of the uterus. [online publication]. Reston (VA): American College of Radiology (ACR); 2007. 6 p. [35 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Hricak H, Akin O, Sala E, Fleischer AC, Bohm-Velez M, Fishman EK, Mendelson E, Thurmond A, Goldstein S, Expert Panel on Women's Imaging. Endometrial cancer of the uterus. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 6 p.

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

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SCOPE

DISEASE/CONDITION(S)

Endometrial cancer of the uterus

GUIDELINE CATEGORY

Evaluation

CLINICAL SPECIALTY

Obstetrics and Gynecology
Oncology
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of radiologic examinations for the evaluation and staging of endometrial cancer of the uterus

TARGET POPULATION

Women with endometrial cancer of the uterus

INTERVENTIONS AND PRACTICES CONSIDERED

1. Magnetic resonance imaging (MRI)
 - Pelvis, with and without contrast
 - Abdomen, with contrast
2. X-ray chest
3. Computed tomography (CT)
 - Pelvis, with contrast
 - Abdomen, with contrast
4. Ultrasound (US)
 - Pelvis transvaginal
 - Hysterosonogram
5. Fluorodeoxyglucose-positron emission tomography (FDG-PET)

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in evaluation and staging

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of recent peer-reviewed medical journals, and the major applicable articles were identified and collected.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed for reaching agreement in the formulation of the appropriateness criteria. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi technique to arrive at consensus. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by the Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible. If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Endometrial Cancer of the Uterus

Variant 1: Newly diagnosed endometrial cancer; diagnostic work-up and staging.

Radiologic Procedure	Rating	Comments	RRL*
MRI pelvis with contrast	8	See comments regarding contrast in the text below under "Anticipated Exceptions."	None
X-ray chest	6		Min
MRI abdomen with contrast	4	See comments regarding contrast in the text below under "Anticipated Exceptions."	None
CT abdomen with contrast	4		Med

Radiologic Procedure	Rating	Comments	RRL*
CT pelvis with contrast	4		Med
US pelvis transvaginal	4		None
<u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Assessing the depth of myometrial invasion.

Radiologic Procedure	Rating	Comments	RRL*
MRI pelvis with contrast	9	See comments regarding contrast in the text below under "Anticipated Exceptions."	None
MRI pelvis without contrast	6		None
CT pelvis with contrast	4		Med
US pelvis transvaginal	4		None
US hysterosonogram	1	Very low risk of malignant cell dissemination into peritoneal cavity.	None
<u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Lymph node evaluation.

Radiologic Procedure	Rating	Comments	RRL*
CT pelvis with contrast	8	Either CT or MRI is appropriate.	Med

Radiologic Procedure	Rating	Comments	RRL*
MRI pelvis with contrast	8	Either CT or MRI is appropriate. See comments regarding contrast in the text below under "Anticipated Exceptions."	None
FDG-PET whole body	5	Applies to stand-alone PET without CT or MRI on all endometrial cancer including grade I. Fusion PET/CT under investigation.	High
US pelvis transvaginal	2		None
<u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 4: Assessing endocervical tumor extent.

Radiologic Procedure	Rating	Comments	RRL*
MRI pelvis with or without contrast	8	See comments regarding contrast in the text below under "Anticipated Exceptions."	None
US pelvis transvaginal	4		None
CT pelvis with contrast	4		Med
<u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Cross-sectional imaging in the pretreatment evaluation of gynecologic cancer patients can play an important role. In cancer of the uterus, it offers an assessment of morphologic prognostic factors, including tumor size, depth of penetration, stage of disease, and lymph node status. Imaging should be viewed

as a complementary tool rather than competitive with the other methods of tumor evaluation (e.g., clinical or surgical assessment).

Clinical Background and Prognostic Factors

Endometrial carcinoma is the fourth most common cancer in women and the leading invasive malignancy in the female genital tract. About 39,080 new cases and 7,400 deaths were expected in the United States in 2007. Endometrial cancer primarily presents at stage I (80% of cases), and the recommended treatment is total abdominal hysterectomy and bilateral salpingo-oophorectomy. Depending on prognostic factors such as depth of myometrial invasion and tumor grade, lymphadenectomy may also be indicated. The major diagnostic factors necessary for the preoperative evaluation of endometrial cancer are:

1. Determination of the risk of lymph node metastasis in order to have subspecialist surgical consultation available.
2. Diagnosis of gross cervical invasion, which requires preoperative radiation therapy or a different treatment plan, (i.e., radical hysterectomy instead of total abdominal hysterectomy).
3. Detection of advanced disease.

The most important prognostic variables for carcinoma of the uterus are the histologic grade and the stage of tumor (see Appendix 1 in the original guideline document), including depth of myometrial invasion and lymph node metastasis. In a study of 1,566 patients with adenocarcinoma of the uterus, the depth of myometrial invasion was found to be the single most important prognostic factor. In stage IA and IB disease, when the tumor is confined to the endometrium or to the superficial myometrium, the incidence of para-aortic lymph node metastases is <2.5%. Conversely, in stage IC disease, when there is deep myometrial invasion, para-aortic lymph node metastases occur in 15%-45%.

The International Federation of Gynecology and Obstetrics (FIGO) staging is not accurate to assess the depth of myometrial invasion or the presence of lymphadenopathy. Because clinical staging carries an overall error in understaging of about 13%-22%, FIGO has recommended routine surgical staging since 1988. Preoperative imaging of endometrial carcinoma can define the extent of disease in order to tailor treatment and indicate referral to a subspecialist if deep myometrial invasion, cervical extension, or lymphadenopathy is suspected. Diagnostic imaging may also be helpful in a primarily obese, elderly population in which radiation therapy rather than surgery might be advocated as a primary treatment or as a preoperative adjuvant to surgery.

Use of Imaging in Clinical Guidelines

Transabdominal and Transvaginal Ultrasound

Transabdominal ultrasound (US) is considered unreliable in staging endometrial cancer. The use of transvaginal US has shown some promise in the evaluation of myometrial invasion. Reported accuracies for myometrial invasion in stage I range from 69%-93% in differentiating deep invasion (stage IC) from absent or superficial invasion (stages IA and IB), and from 68%-69% in differentiating stage IA from stage IB from stage IC. A study using high-frequency transvaginal US

showed a similar accuracy of 73% in assessing myometrial invasion. However, studies directly comparing the accuracy of transvaginal US to that of contrast-enhanced magnetic resonance imaging (MRI) for staging have consistently demonstrated that the latter performs with greater accuracy.

In addition, there are insufficient reports about the value of transvaginal US in predicting cervical extension, parametrial invasion, or lymphadenopathy. In one study, transvaginal US showed cervical involvement in only 7 of 10 patients with cervical extension.

Hysterosonography, (i.e., transvaginal US evaluation of the uterus after intracavitary saline infusion), has been considered as an imaging modality for evaluating deep myometrial invasion with accuracy of 89% (17/19) in one series. However, recent reports indicate that the procedure disseminates malignant cells into the peritoneal cavity in 6%-7% of patients with an established diagnosis of endometrial cancer. Although there is no evidence that this dissemination increases rates of intraperitoneal metastases, these results imply that hysterosonograms have the potential to upstage a patient from disease confined to the uterus (stage I or II) to stage III thereby altering postsurgical treatment and follow-up algorithms. While use of hypertonic saline has been proposed to induce cell lysis and potentially decrease or eliminate the risk of peritoneal spread, this has not yet been practically demonstrated in the literature.

Computed Tomography

Computed tomography (CT) has been used for evaluating endometrial carcinoma, with emphasis on evaluating the depth of myometrial invasion and assessing lymph node status. In studies comparing CT with US or MRI, the accuracy of CT for myometrial invasion is reported to be from 58%-61% versus 68%-69% in US and 88%-89% in MRI. One study found no significant difference between helical CT and US for diagnosing deep myometrial invasion. The value of CT in diagnosing cervical extension is not evident, because an easy identification of the margin between the cervix and the uterine corpus is difficult on axial imaging planes. Moreover, most reports suffer from having a few patients with stage II, which may prevent valid conclusions to be drawn. Preoperative evaluation of multidetector CT (MDCT) for staging endometrial carcinoma has not as yet been evaluated in randomized prospective controlled trials.

Magnetic Resonance Imaging

MRI is significantly superior to US in the evaluation of both tumor extension into the cervix and myometrial invasion. A meta-analysis study showed that the efficacy of contrast-enhanced MRI is significantly better than that of US, CT, or noncontrast MRI in evaluating the depths of myometrial invasion in patients with endometrial cancer. Contrast-enhanced MRI performs significantly better than unenhanced MRI for evaluation of the depth of myometrial invasion. The superiority of MRI compared to CT and clinical staging has also been documented. MRI provides the most accurate and consistent evaluation of patients with endometrial cancer. The overall staging accuracy of MRI has been reported to be between 85%-93%. The efficacy of MRI is improved with the use of dynamic contrast-enhanced imaging. The assessment of the depth of myometrial invasion shows significant improvement with the use of dynamic scanning (accuracy of

55%-77% for noncontrast images versus 85%-91% for contrast-enhanced images). Compared with T2-weighted images, the use of contrast media will reduce both overestimation as well as underestimation of depth of myometrial invasion. An erroneous MRI assessment of the depth of myometrial invasion can sometimes be ascribed to as large polypoid endometrial cancer, which distends the uterus so that the thin rim of myometrium is stretched over it rather than deeply infiltrated. Cervical extension can be diagnosed reliably with accuracy ranging from 86%-95%. One study comparing MRI with fractional curettage and hysteroscopy showed that MR imaging had the highest sensitivity (91%) and specificity (96%) for diagnosing cervical involvement in endometrial cancer. A recent meta-analysis showed that use of contrast-enhanced MRI significantly affects the post-test probability of deep myometrial invasion in patients with all grades of endometrial cancer and could be used to select patients for specialist referral.

Lymphangiography

Lymphangiography is not recommended for evaluating cancer of the endometrium. Not only because it is invasive (and very few imaging centers offer this service) but also, because of the difficulties in the evaluation of pelvic nodes, its performance is not reproducible and, even performed optimally, slightly inferior to that of CT and MRI.

Positron Emission Tomography

The role of positron emission tomography (PET) in endometrial cancer imaging is still under investigation. In detecting lymph node involvement by tumor, PET performs with accuracy (95%) comparable to that of CT or MRI. However, because 45% of endometrial cancer is stage I and not fluorodeoxyglucose (FDG)-avid, the reported improved sensitivity of PET (60%-86%) is only true for nodes >1 cm. This limitation, coupled with the limitations of PET in assessing intraperitoneal tumor implants and parenchymal metastases makes CT and MRI preferable in detecting extrauterine disease. PET was reported to be useful in the post-therapy surveillance, both for localizing suspected recurrences and for detecting asymptomatic recurrent disease. A study showed that in the detection of recurrence and the evaluation of treatment response, FDG-PET, with help by CT and/or MRI, performed better (sensitivity 100%, specificity 88.2%, and accuracy 93.3%) compared with CT and/or MRI (sensitivity 84.6%, specificity 85.7%, and accuracy 85%) and tumor markers (i.e., CA125, CA19-9, CEA, and sialyl TN antigen, (sensitivity 100%, specificity 70.6%, and accuracy 83.3%). The results of FDG-PET correlated well with the clinical outcome of the patients, with patients having negative PET results tending to show disease-free courses.

Recommended Imaging Approach

Because contrast-enhanced MRI demonstrates the highest accuracy for overall staging of endometrial cancer, it should be used, when available, as the preferred modality for treatment planning. Transvaginal US can be used to assess the depth of myometrial invasion and cervical involvement, albeit with less accuracy than MRI. CT and MRI perform equivalently for assessing nodal involvement. PET is promising in the post-treatment surveillance of endometrial cancer patients.

However, there are no outcome studies or cost-effectiveness analyses on imaging evaluation of endometrial cancer.

Summary

Patients with endometrial carcinoma should undergo diagnostic imaging only in cases of clinical staging difficulties, including those with medical comorbidities that preclude surgery, large tumors, high histologic tumor grade, or possible cervical involvement. If imaging is needed, MRI is the most accurate technique and should be the preferred modality.

Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF, also known as nephrogenic fibrosing dermopathy) was first identified in 1997 and has recently generated substantial concern among radiologists, referring doctors and lay people. Until the last few years, gadolinium-based MR contrast agents were widely believed to be almost universally well tolerated, extremely safe and non-nephrotoxic, even when used in patients with impaired renal function. All available experience suggests that these agents remain generally very safe, but recently some patients with renal failure who have been exposed to gadolinium contrast agents (the percentage is unclear) have developed NSF, a syndrome that can be fatal. Further studies are necessary to determine what the exact relationships are between gadolinium-containing contrast agents, their specific components and stoichiometry, patient renal function and NSF. Current theory links the development of NSF to the administration of relatively high doses (e.g., $>0.2\text{mM/kg}$) and to agents in which the gadolinium is least strongly chelated. The U.S. Food and Drug Administration (FDA) has recently issued a "black box" warning concerning these contrast agents (<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm142882.htm>).

This warning recommends that, until further information is available, gadolinium contrast agents should not be administered to patients with either acute or significant chronic kidney disease (estimated glomerular filtration rate [GFR] $<30\text{ mL/min/1.73m}^2$), recent liver or kidney transplant or hepato-renal syndrome, unless a risk-benefit assessment suggests that the benefit of administration in the particular patient clearly outweighs the potential risk(s).

Abbreviations

- CT, computed tomography
- FDG-PET, fluorodeoxyglucose-positron emission tomography
- Med, medium
- Min, minimal
- MRI, magnetic resonance imaging
- US, ultrasound

Relative Radiation Level	Effective Dose Estimated Range
None	0

Relative Radiation Level	Effective Dose Estimated Range
Minimal	<0.1 mSv
Low	0.1-1 mSv
Medium	1-10 mSv
High	10-100 mSv

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Selection of appropriate radiologic imaging procedures for the evaluation and staging of endometrial cancer of the uterus

POTENTIAL HARMS

- Recent reports indicate that hysterosonography disseminates malignant cells into the peritoneal cavity in 6%-7% of patients with an established diagnosis of endometrial cancer. Although there is no evidence that this dissemination increases rates of intraperitoneal metastases, these results imply that hysterosonograms have the potential to upstage a patient from disease confined to the uterus (stage I or II) to stage III, thereby altering postsurgical treatment and follow-up algorithms.
- Some patients with renal failure who have been exposed to gadolinium contrast agents (the percentage is unclear) have developed nephrogenic systemic fibrosis (NSF), a syndrome that can be fatal. The U.S. Food and Drug Administration (FDA) has recently issued a "black box" warning concerning these contrast agents. This warning recommends that, until further information is available, gadolinium contrast agents should not be administered to patients with either acute or significant chronic kidney disease (estimated glomerular filtration rate [GFR] <30 mL/min/1.73m²), recent liver or kidney transplant or hepato-renal syndrome, unless a risk-benefit assessment suggests that the benefit of administration in the particular patient clearly outweighs the potential risk(s).

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Additional information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR) Appropriateness Criteria® Radiation Dose Assessment Introduction document (see "Availability of Companion Documents" field).

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 (revised 2007)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Women's Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Susanna I. Lee MD, PhD; Rochelle F. Andreotti, MD; Teresita L. Angtuaco, MD; Arthur C. Fleischer, MD; Mindy M. Horrow, MD; Marcia C. Javitt, MD; Anna S. Lev-Toaff, MD; Leslie M. Scoutt, MD; Carolyn Zelop, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [American College of Radiology \(ACR\) Web site](#).

ACR Appropriateness Criteria® *Anytime, Anywhere*™ (PDA application). Available from the [ACR Web site](#).

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the [American College of Radiology \(ACR\) Web site](#).
- ACR Appropriateness Criteria® radiation dose assessment introduction. American College of Radiology. 2 p. Electronic copies: Available from the [American College of Radiology Web site](#).

PATIENT RESOURCES

None available

NGC STATUS

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